Solid Phase System for the Immobilization of Human Erythrocytes

Manufacturer: Immucor.Inc.
Norcross, GA 30071 USA

EC REP Authorized Representative: Immucor Belgium S.A.
6220 Charleroi BELGIUM

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IMMUCOR GAMMA®

Intended Use:

The Capture-R® Select Solid Phase System provides modified microwells for the immobilization of human erythrocytes for use in solid phase assays for the detection of IgG red cell antibodies to corresponding red cell antigens (e.g., antibody screening, selected red cell panels, crossmatching, or antigen phenotyping).

Summary of the Test:

Many blood group antibodies of the IgG class bind to (sensitize) red cells but are not capable, once bound, of causing red cell agglutination. Detection of sensitizing IgG antibodies is dependent on the use of an antiglobulin reagent or the use of Capture R solid phase technology for the detection of IgG red cell antibodies. Capture-R Select is employed to allow the user to perform in vitro testing of serum or plasma or qualified red cell typing antiserum for the detection of IgG antigen/antibody interactions. User selected red cells that are bound to the Capture-R Select Microwell Strips are incubated with test sera, plasma or reagent under conditions that will facilitate antigenlantibody interaction. Capture-R Select results can be applied to antibody screening, crossmatching or antibody identification problem resolution and red cell antigen phenotyping.

Principle of the Test

Capture-R assays are based upon the procedure of Plapp et al.[1] and Juji et al [2]. Red cells are first immobilized on the surface of polystyrene microwells. The antigens carried on the immobilized red cells are used to capture red cell-specific IgG antibodies Following incubation, unbound residual immunoglobulins are rinsed from the wells and anti-IgG-coated indicator red cells are added. Centrifugation brings the indicator red cells in contact with antibodies bound to the immobilized red cell layers. In the case of a positive test, IgG-anti-IgG complexes form between the indicator red cells and the sensitized, immobilized cells. As a consequence of antibody bridging, the indicator cells adhere to the immobilized cells as a second immobilized layer. In the absence of detectable antigen-antibody interactions (negative test), the indicator red cells do not bind to the immobilized cells and pellet to the bottom of the wells as tightly packed cell buttons.

For selected cell panels, reagent red cells are bound to the test wells and incubated with the patient's serum. The pattern of positive and negative results obtained at test completion is used to assist in the detection or identification of red cell antibody(ies) (i.e. supplement to Capture-R Ready ID).

In crossmatch tests, donor red cells are bound to Capture-R Select test wells. The cells are then incubated in the presence of patient (recipient) serum or plasma. Positive tests indicate the recipient has produced antibodies to antigens present on the donor red cells. A negative test indicates the absence of detectable IgG antibody to donor antigens.

In antigen phenotyping tests, donor or patient red cells are bound to Capture-R Select test wells. The bound red cells are incubated with a selected antiserum and may be tested in parallel with an autologous control. Positive tests with the selected antiserum indicate the presence of the corresponding antigen if the autolgous control is negative. A positive reaction with the autologus control indicates an invalid test. A negative test with both the antiserum and autolgous control indicates the absence of corresponding red cell antigen.

Reagents:

Capture-R Select Microwell Strips: strips of wells coated with an immunologic agent to immobilize red cells to the microwell surface. Twelve 1x 8 strips are packaged with a support frame and enclosed in a foil pouch to which a desiccant and moisture indicator have been added. Each plate or strip is ready to be used as supplied. Capture-R Select Strips are packaged in moisture resistant pouches. Store the strips at 1-30 C. Strips can be used singly or in multiples. Unused strips, desiccant and humidity indicator should be immediately and carefully resealed within the foil pouch to prevent exposure to moisture that can destroy the immunologic binding agent. Strips within resealed pouches should not be used if the humidity indicator shows the presence of moisture by turning from blue to pink. Strips removed from pouches should be used within 16 hours.

Capture **LISS:** a buffered low ionic strength solution containing bromcresol purple dye and 0.1% sodium azide as a preservative.* Store at 1-10 C.

Capture-R Ready Indicator Red Cells: a suspension of red cells coated with murine monoclonal anti-human IgG molecules. The reagent is suspended in a buffered preservative solution to which chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL) and gentamycin sulfate (0.05 mg/mL) have been added as preselvatives. Store at 1-10 C. It is normal for the Indicator Red Cells to aggregate slightly during storage at 1-10 C.

Capture-R Positive Control Serum (Weak): containing antibodies to red cells. Contains sodium azide (0.1%) as a preservative* Store at 1-10 C.

Capture-R Negative Control Serum: containing no antibodies to red cells. Contains sodium azide (0.1%) as a preservative*. Store at 1-10 C.

The in-date components (Capture-R Select Strips, Capture-R Ready Indicator Red Cells, Capture LISS and Capture-R Control Sera) of one lot can be used interchangeably with those of other lots, irrespective of their lot numbers, provided the components are within their dating periods.

Precautions:

1. For in vitro diagnostic use.
2. This reagent contains 0.1% sodium azide and is classified as Harmful (Xn). R22 Harmful if swallowed.

Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into the sink, flush with a large volume of water to prevent azide build-up.

3. Bring all Capture-R components to 18-30 C before testing. Failure to warm this reagent properly will result in aberrant test results.
4. Suspend Capture-R Ready Indicator Red Cells before use by gently inverting each vial several times. It is normal for Capture-R Ready Indicator Red Cells to aggregate slightly during 1-10 C storage.
5. Capture-R Ready Indicator Red Cells should not be used if the cells darken from red to brown, if there is hemolysis, or if the cells fail to perform in positive control tests. Slight hemolysis may occur with age.
6. Turbidity of Capture LISS and Capture-R Control reagents may be an indication of microbial contamination. Reagents that are microbially contaminated should not be used.
7. Do not use reagents beyond their expiration dates. Leaking vials should not be used.
8. The format for the expiration date is expressed as CCYY-MM-DD (year-month day).
9. Handle and dispose of reagent as if potentially infectious.
10. Red cell samples should be washed if hemolysis is apparent.

CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH

CURRENT FDA RECOMMENDATIONS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS. THE PACKAGING OF THIS PRODUCT (DROPPER BULBS) CONTAINS DRY NATURAL RUBBER.

Specimen Collection and Preparation:

Plasma or Serum: Draw a blood specimen using an acceptable phlebotomy technique. Fresh serum or plasma (EDTA, ACD, CPD, CPDA-1, CP2D) may be used in this assay. EDTA samples should be used within 14 days of collection. Testing should be performed as soon as possible following collection *to* minimize the chance that falsely positive or falsely negative reactions will occur due to improper storage or contamination of the specimen. Serum or plasma that cannot be tested within 24 hours should be stored at 1-10 C if possible. Alternatively, serum or plasma can be separated from red cells and stored frozen. Weakly reactive antibodies may deteriorate and become undetectable in samples stored at room temperature for several days before testing or in samples stored for prolonged periods at 1-10 C. Do not use samples drawn into tubes with neutral gel separators. False-positive results may occur with such samples.

NOTE: Samples exhibiting slight to moderate hemolysis must be washed prior to use. Samples exhibiting severe hemolysis cannot be used for monolayer preparation.

Donor/Patient red cells: Obtain red cells from samples collected with an anticoagulant (EDTA, ACD, CPD, CPDA-1 or CP2D). For semiautomated methods it is recommended that red cells be obtained from anticoagulated samples. Samples that cannot be tested within 24 hours should be stored at 1-10 C as soon as possible. Best results will be obtained if EDTA red cells are used within 14 days, and ACD, CPD, CP2D or CPDA-1 red cells are used within 35 days. Red cells drawn in other anticoagulants bind well to test wells if used up to the expiration of the anticoagulant. Red cells obtained from samples beyond expiration may not adhere properly *to* Capture-R Select microwells. (See LIMITATIONS)

Reagent red cells: Obtain reagent red cells from commercially prepared antibody screening or identification reagents. Best results will be obtained if the reagent red cells are used within their expiration periods. (See LIMITATIONS) Reagent red cells should be suspended in Immucor red cell diluent.

Antiserum for red cell phenotyping: Plasma, serum or manufactured reagent containing IgG antibody to a corresponding red cell antigen may be used for red cell phenotyping. It is the user's responsibility to determine the suitability of the antiserum as a phenotyping reagent unless specific claims are provided by the manufacturer for its use by Capture R solid phase assays. It is recommended that the user verify the reactivity and specificity of the antiserum to determine its suitability. (See LIMITATIONS)

Procedure:

Materials Provided:

Capture-R Select Microwells in a resealable pouch.

Materials required but not provided with Capture-R Select

1. Capture LISS in dropper vials
2. Capture-R Ready Indicator Red Cells in dropper vials
3. Capture-R Positive Control Serum (Weak) in dropper vials
4. Capture-R Negative Control Serum in dropper vials

Additional materials required:

All methods:

1. Donor or patient plasma (or serum in manual tests) or antigen phenotyping antiserum-(containing an IgG component), if applicable
2. Donor, patient or reagent red cells
3. Stop watch or interval timer
4. Illuminated surface
5. Marking pens

Manual or semiautomatic methods:

1. Transfer pipettes or pipetting system
2. Centrifuge with rotor and carriers capable of accommodating 1 x 8 stripwells'
3. 37 C heat block or dry bath incubator
4. Phosphate-buffered (approximately 15 mM) isotonic saline, pH 6.5 - 7.5
5. Semiautomatic or automatic microplate washer, wide port saline wash bottle or manual dispensing manifold*
6. Dispensing manifold or pipettors designed for microplates
7. Blank stripwells for balance

* It is the users responsibility to validate an accessory device (either listed or otherwise) for its intended use. Validation results should be maintained as part of the laboratory's records for review by regulatory agencies.

Test **Methods:**

Manual or Semiautomatic Methods

1. Bring all Capture reagents and samples to 18-30 C before testing.
2. Remove a Capture-R Select Microwell Strip from its protective pouch. Inspect the humidity indicator enclosed within the pouch. If the humidity indicator shows the presence of moisture, do not use any strip in the pouch. In the absence of signs of moisture, return the humidity indicator, desiccant and unused strips *to* the pouch and carefully reseal the pouch.
3. Check the bottom tab of the strip. Do not use the strip if the tab is not printed with 'SC' *to* show the test identification.
4. Place the strip in a frame holder. Note: the strip will fit snuggly into its holder only in the correct orientation.
5. Anti-coagulated, whole blood (no! centrifuged), or reagent red cells may be used as the cell sample. If whole blood is used as the cell sample, two drops (100 ± 10 uL) of phosphate-buffered isotonic saline should be added *to* the well prior *to* sample addition. Note that red cells should be free of hemolysis. Fragmented RBC membranes will interfere with cell monolayer formation. If the red cell sample shows signs of degradation, i.e., slight *to* moderate (1+ - 2 +) hemolysis, wash sample red cells at least 2 times with buffered saline and resuspend the cells *to* the approximate original sample volume in buffered saline. Samples exhibiting severe hemolysis (≥3+) cannot be used. In date reagent red cells free of evidence of hemolysis, should be diluted to approximately 2-4% in buffered saline.
6. Add one drop of any patient, donor or reagent red cell sample *to* two wells of the strip. These wells will serve as positive and negative run control wells.
7. To the remaining wells add one drop of the red cells from the red cell samples to be tested. If an autologous control is desired, add one drop of the red cells from the red cell sample(s) into an additional well(s). If performing antigen phenotyping, add one drop of two different red cells with the appropriate antigenic make-up to two wells. These will serve as the controls for the anti-serum.
8. Agitate the plates *to* mix the cells.
9. Centrifuge the wells:
   450-600 x g for 5 minutes" - samples from anti-coagulated whole blood (3045%)
   190450 x g for 5 minutes" - samples from 2-4% red cells
10. Agitate the plates to remove unattached cells.
11. Remove the excess unbound red cells by washing the strip as follows:

Manual washing technique

A. Decant the wells thoroughly by manually inverting the plate over a sink or waste receptacle and with several rapid, sharp motions, dumping the liquid contents from the wells.

B. Fill the wells with saline dispensed from a multichannel dispenser or manifold designed for microwell plates. Alternatively, a saline wash bottle can be used *to* dispense the saline. Saline should not be added with excessive force since this may cause the red cell monolayer, as well as unbound cells, *to* disengage from the plate. Wash the wells a minimum of six times with saline. Decant between each wash as in step 11A above.

C. Examine the well bottoms following each wash to determine the suitability of the test wells. Properly immobilized red cells should give the well bottoms a uniformly reddish opaque appearance, without the presence of streaming. Streaming is an indication that unbound red cells remain. Wells should be further washed until no streaming occurs.

CAUTION: Excessive or vigorous washing techniques may dislodge or create holes in the immobilized layer. As a consequence, falsely positive test results will be obtained at the end of the procedure.

Automated washing

A. Prime the instrument and intake lines with saline according to the instrument manufacturets directions.

B. To remove the excess unbound red cells from the Capture-R Select microtitration plate aspirate the contents of each well with a vacuum device.

C. Sequential aspiration/dispense washers: Wash each well a minimum of three times by filling each well with at least 300 uL of saline and then aspirating the well contents with a vacuum device. Consult the instrument manufactureh operating manual for a description of the proper use of the plate washing device. After the first washes have been completed, rotate the strip 180 degrees and wash a minimum of three more times. In the event one of the dispensing or aspiration probes of the washer has become clogged, this increases the likelihood that all wells will be washed sufficiently. **NOTE:** The automated washing device must be adjusted such that approximately 4-8 uL of saline remains in each well after aspiration. Wells should not be aspirated until

they are dry. Remove the strip from the instrument. Inspect the red cell monolayers for holes. Holes in the same position of all or most monolayers indicate that the washer aspiration probes have not been set far enough away from the well bottoms or that the washer dispensing pressure is too high.

D. CSW100 continuous aspiration/dispense washer: Select the number of strips to be washed. Select program P1. Press the start button. At the completion of the automated washing cycle, remove the plate from the washer.

NOTE: Patchy holes placed irregularly over the bottoms of some or all wells is are often an indication that the Capture-R Select Microwell Strip has been improperly washed. However, it may also indicate that the strip being used is defective or that the red cells have hemolyzed. Discard the strip. Wash the red cells. Prepare monolayers on a new strip. If patchy, irregularly shaped holes continue to be seen, discontinue testing. Notify your Immucor service representative immediately. If no holes are observed in the monolayers proceed with testing.

IIa. Antibody Screening, Selected Red Cell Panels, Crossmatching:

1. Immediately add 2 drops (100 ± 5 µL) of Capture LISS to each well,
2. Add one drop (50 ± 5 µL) of test sera to all test wells of the strip. NOTE: The purple blue color of the Capture LISS will change to sky blue or turquoise in the presence of serum or plasma. Failure to change color may indicate that test serum/plasma has inadvertently been omitted from the well.
3. Add 1 drop (50 ± 5 µL) of Capture-R Positive Control Serum (Weak) to the positive run control well.
4. Add 1 drop (50 ± 5 µL) of Capture-R Negative Control Serum to the negative run control well. NOTE: If more than one strip is needed to test patient or donor samples, additional strips may be used without including control reagents, up to one full frame holder. Note: At least one set of control reagents (Weak Positive and Negative Controls) should be included with each test run or each completed frame holder to control for improper washing or centrifugation.

IIb. Antigen Phenotyping

1. Immediately add 2 drops (100 ± 5 µL) of Capture LISS to each well.
2. Add one drop (50 ± 5 µL) of test sera to all test wells of the strip. NOTE: The purple blue color of the Capture LISS will change to sky blue or turquoise in the presence of serum or plasma. Failure to change color may indicate that test serum/plasma has inadvertently been omitted from the well. Due to the nature of the diluent some commercially prepared anti-serum may not cause the expected color change.
3. If performing an autologous control, add one drop (50 ± 5 µL) of the patient/donor sera to the appropriate well
4. Add 1 drop (50 ± 5 µL) of Capture-R Positive Control Serum (Weak) to the positive run control well.
5. Add 1 drop (50 ± 5 µL) of Capture-R Negative Control Serum to the negative run control well. NOTE If more than one strip is needed to test patient or donor samples, additional strips may be used without including control reagents, up to one full frame holder, Note: At least one set of control reagents (Weak Positive and Negative Controls) should be included with each test run or each completed frame holder to control for improper washing or centrifugation.
6. Add one drop of anti-sera to the negative and positive anti-sera control wells.
12. Incubate the strip at 36-38 C for no less than 15 and no more than 60 minutes.† Add 5 minutes to the minimum incubation period if a dry heat incubator is used.
13. Wash the serum-LISS mixture from the strip using a manual or automated wash technique as described in **step** 11.
14. Add 1 drop (50 ± 5 µL) of Capture-R Ready Indicator Red Cells to each of the wells.
15. Immediately centrifuge the strip at approximately 600-1000 x g for 2 minutes.*
16. Place the strip on an illuminated surface and examine for adherence or the absence of Indicator Red Cell adherence. For test results to be considered valid, the following reactions must be obtained with the control wells.

Run Controls:

If the correct reactions are not obtained with the Capture-R Control Sera each time a plate is tested, test results are invalid and all tests in the run must be repeated.

- Positive Control (Weak) = adherence of Capture-R Ready Indicator Red Cells to part or all of the reaction surface.
- Negative Control Serum = tight button of Capture-R Ready Indicator Red Cells at the bottom of the test wells with no area of adherence.

If the correct reactions are not obtained with the anti-serum controls **test** results are invalid and all tests in the run must be repeated.

- Positive anti-serum control = adherence of Capture-R Ready Indicator Red Cells to part or all of the reaction surface.
- Negative anti-serum control = tight button of Capture-R Indicator Red Cells at the bottom of the test well with no area of adherence.

If a negative reaction is not obtained with the autologous control (if performed) the test results for the corresponding sample are invalid and the test(s) must be repeated.

- Negative autologus control = tight button of Capture-R Indicator Red Cells at the bottom of the test well with no area of adherence.

*The g forces and time given are approximations of forces required to produce the desired degree of adherence. The appropriate g forces (or rpm's) and centrifugation times must be determined individually for each centrifuge used.

Stability of the Reaction:

Following centrifugation, manually or semiautomatically performed tests can be read immediately. Since positive reactions are permanent, wells can be covered following centrifugation to prevent evaporation, stored at 1-10 C, and read or reread up to 2 days following testing.

Capture-R Select Daily Quality Control:

- Manual or semiautomatic testing: Daily Quality Control of all Capture-R Select components should be performed by the inclusion of the Capture-R Positive and Negative Control Sera. These sera should be included with each strip run to ensure that neither technical errors, nor reagent failures, have occurred. Continued failure of the Control Sera to perform properly on repeated testing may indicate that one or more of the Capture-R test reagents has deteriorated, or that the test is consistently being performed incorrectly.
- Red Cell Phenotyping Antiserum: Daily Quality Control of selected Red Cell Phenotyping Antiserum should be performed to confirm the reactivity and the specificity of the reagent. These reagents should be tested with the corresponding antigen positive red cells (preferably heterozygous expression) and antigen negative red cells. The reagent can be considered appropriate for use if only antigen positive red cells demonstrate a positive result.

Interpretation of Results:

- Negative test: tight button of Capture-R Ready Indicator Red Cells at the bottom of the test well with no area of adherence.
- Positive test: adherence of Capture-R Ready Indicator Red Cells to part or all of reaction surface or enlargement of the cell button over that of the negative control.

Limitations:

Not for use on the ABS2000.

The crossmatch (IgG) using Capture-R Select is intended only for the detection of incompatibilities due to IgG antibodies. The RBC crossmatch (IgG) is not intended for the detection of incompatibilities due to IgM antibodies, such as ABO incompatibilities. If the detection of incompatibilities due to IgM antibodies are necessary, then the crossmatch (immediate spin) must be used.

Erroneous test results can occur from bacterial or chemical contamination of test materials, inadequate incubation periods, improper centrifugation, inadequate washing of test wells, or omission of test reagents or steps.

Overcentrifugation of manual or semiautomated tests, following addition of the Capture-R Ready Indicator Red Cells, may result in falsely negative or doubtful positive reactions due to the collapse of the adherent indicator cell layer.

The deceleration parameters of the centrifuge in use may affect the type of reactions obtained at the end of the assay. Failure to apply the braking mechanism in units with long deceleration times may result in falsely negative reactions. Conversely, braking of centrifuges with short deceleration times may also cause erroneous test results. It is the user's responsibility to evaluate centrifuge performance before use to identify optimum spin speeds, spin times and acceleration/deceleration settings. The results of the performance evaluation should be maintained as part of the laboratory's records for review by regulatory agencies.

Addition of Capture-R Ready Indicator Red Cells in excess of amounts described in this insert may result in falsely negative or doubtful test reactions. Addition of too few indicator red cells, as might occur with improper mixing of the reagent or through hemolysis of the cells, will cause weak falsely positive results. Indicator red cells that are colder than 18 C when used will cause weak false-positive results.

Serum or plasma samples obtained from tubes containing neutral gel separators may produce falsely positive results in antibody screening tests. Tubes with gel separators are not designed for blood bank use.

'Commercial anti-sera or antibodies derived from other sources that are formulated to 'react in a test tube may show unexpected positive or negative reactivity by this method.

Red cells that are positive in a direct antiglobulin test will produce a false positive result. For a positive result to **be** considered valid, a corresponding autologous control must **be** negative.

Contamination of Capture-R Ready Indicator Red Cells with IgG-containing serum or plasma proteins will neutralize the anti-IgG component of the Capture-R Ready Indicator Red Cells, leading to falsely negative test results. Failure of the Capture-R Positive Control is an indication of neutralization in manual or semiautomated testing..

Examples of pure IgG4 subclass antibodies may not be detected by the Capture-R Ready Indicator Red Cell reagent. Note, however that pure IgG4 antibodies are very uncommon.

Antibodies such as anti-M, -P_1, -Le^a and -Le^b frequently react in tube hemagglutination tests at the room temperature phase of testing rather than at 37 C or at the antiglobulin phase. Some workers have interpreted this to mean that the antibodies were composed mostly of saline-reactive IgM molecules. Examples of these antibodies may be detected in Capture-R assays, even though the test system is designed primarily for the detection of IgG. Some of these antibodies may **be** detected by Capture-R Ready Indicator Red Cells because they contain an IgG component Others may be detected, **not** because they are IgG in nature, but because the Indicator Red Cells carry the antigen toward which the IgM antibody is directed. Some IgM antibodies have been found to link Indicator Red Cells to immobilized red cell monolayers by binding to antigens on both. Thus, examples of anti-M, -Le^a, -Le^b, -P_1, etc that are detected in Capture-R tests should not **be** assumed to contain an IgG component without further study. These specificities are regarded as insignificant in most clinical situations. Examples of these antibodies detected in Capture-R tests are not necessarily more significant than examples that fail to react. Specificities of presumed significance, that are entirely IgM in nature (ie, IgM anti-K or a IgM anti-E) may fail to react in this assay.

Some IgG antibodies have been shown to react poorly in solid phase red cell adherence assays. These include examples of antibodies to Bg^a, Bg^b, Kn^a, Cs^a, Yk^a, JMH, McC^a, Ch and Rg.[3,4]

Low ionic strength solutions (LISS) have been shown to enhance many antigen-antibody interactions. However, sera may be encountered that contain antibodies that are not optimally reactive in LISS test systems including the Capture-R assay.

Red cells will not adhere properly to Capture-R test wells in the following situations: 1) when they are suspended in a diluent contaminated with free hemoglobin or 2) if they are beyond the expiration of the sample diluent or anticoagulant. Non-adherence can often be corrected by washing the red cells one or two times with saline.

Pooled reagent red cells will not be as sensitive as unpooled single donor red cell samples at detecting antibodies. Pooled reagent red cells should not be used in antiglobulin antibody screening tests to replace the antiglobulin crossmatch.

Negative reactions will be obtained if the test serum contains antibodies present in concentrations too low to be detected by the test methods employed.

No one test method is capable of detecting all antibodies

Incorrect results may **be** obtained in Capture-R system assays if testing personnel are not adequately trained in proper test performance. A laboratory that institutes Capture-R technology should have a program that will properly train personnel. After personnel have received sufficient training, but before existing antibody detection techniques are replaced with Capture-R, the laboratory should perform parallel evaluations With Capture-R assay systems and the house method (using a large battery of known positive and negative samples) to document that the appropriate results can be obtained.

Specific Performance Characteristics:

The performance characteristics of the Capture-R Select test system were established in parallel evaluations with Modified Capture-R and tube hemagglutination methods. Results of these studies demonstrate the Capture-R Select assay has similar specificity and sensitivity upon testing samples known to contain IgG antibodies specific to red cell antigens.

To ensure suitable adherence of red cells and test performance, each lot of Capture-R Select is tested prior to release with reagent red cells and with reference sera known to contain IgG antibodies as well as sera known to be free of red cell-specific antibodies.

The performance of this product **is** dependent upon adhering to the insert's recommended methodology. Additional information regarding testing performed at the time of manufacture may be furnished upon request by consulting Immucor's Technical Service at 800-492-BLUD (2583) or 770-441-2051.

No US standard of potency exists for this product.

Bibliography:

1. Plapp FV, Sinor LT, Rachel JM, et al. A solid phase antibody screen. Am J Clin Pathol 1984;82:719.
2. Jugi T, Kano K, Milgrom **F.** Mixed agglutination with platelets. Int Arch Allergy 1972;42:474.
3. Beck ML, Rachel JM, Sinor LT, **et al.** Semiautomated solid phase adherence assays for pretransfusion testing. Med Lab Sci 1984;41:374.
4. Rolih SD, Eisinger RW, Moheng MC, et al. Solid phase adherence assays: alternatives to conventional blood bank tests. Lab Med 1985;16:766.

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